



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1505.28
True Name	Equine Influenza Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Calvenza-03 EIV - Boehringer Ingelheim India Pvt Ltd Calvenza-03 EIV - No distributor specified
Date of Compilation Summary	February 06, 2019

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Equine influenza virus
Study Purpose	Demonstration of efficacy against Equine influenza NewMarket strain NM/2/93
Product Administration	
Study Animals	Horses
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 13, 2000

Study Type	Efficacy
Pertaining to	Equine influenza virus
Study Purpose	Demonstration of efficacy against Equine influenza Kentucky strain KY95
Product Administration	
Study Animals	Horses
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 13, 2000

Study Type	Efficacy
Pertaining to	Equine influenza virus
Study Purpose	Demonstration of efficacy for updated Equine influenza Ohio/03 strain
Product Administration	
Study Animals	Horses
Challenge Description	
Interval observed after challenge	
Results	This product class allows the manufacturer to update microorganisms in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support influenza strain updates to the product composition were evaluated by USDA-APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination-challenge studies may not have been required for these updates.
USDA Approval Date	January 22, 2008

Study Type	Efficacy
Pertaining to	Equine influenza virus
Study Purpose	Demonstration of efficacy against Equine influenza virus NewMarket strain NM77
Product Administration	
Study Animals	Horses
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 13, 2000

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions in horses including pregnant mare
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 26, 2001